Attorney Docket No. A35066 072261.0131
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentee : Hagen et al.

Patent No. : 4,780,950

Granted : November 15, 1998

For : Expression of Factor VII Activity in Mammalian Cells

REQUEST FOR CORRECTION OF NOTICE OF FINAL DETERMINATION AND EXPEDITED ISSUANCE OF CERTIFICATE OF PATENT TERM EXTENSION

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper for Patent No. 4,780,950 is being facsimile transmitted to the Patent and Trademark Office on the date indicated below.

April 5, 2004
Date of Deposit

Lisa B. Kole
Attorney Name

35,225
Registration No.

Signature

April 5, 2004
Date of Signature

Attention: Ms. Karen Ferriter

Mail Stop Patent Extension
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir:

It has come to the attention of the Patentee that the Notice of Final Determination dated March 22, 2004 does not list the correct owner of the above-referenced patent. The correct owner of the patent is Novo Nordisk Health Care AG. Attached is a marked-up copy of the Notice of Final Determination.

Attorney Docket No. A35066 072261.0131
PATENT

The attached Notice of Final Determination shows the error corrected in red ink as follows:

Under the heading "Owner of Record", please **replace** "ZymoGenetics, Inc." with

--Novo Nordisk Health Care AG--.

In support of this correction, Patentee submits a copy of a (1) Notice of Recordation of Assignment Document dated March 30, 2004, (2) Recordation Form Cover Sheet dated March 24, 2004, and (3) Assignment of Patents and of June 1, 1984 Agreement Relating to Human Blood Coagulation Factors as Amended, which assigns the above-referenced patent from ZymoGenetics, Inc. to Novo Nordisk Health Care AG. The assignment document was recorded at the Assignment Branch at the USPTO on March 24, 2004. Therefore, Patentee submits that the correct owner of record for the above-referenced patent is Novo Nordisk Health Care AG.

Patentee requests the issuance of a corrected Notice of Final Determination.

In accordance with the correction, please list Novo Nordisk Health Care AG as the owner of record for the above-referenced patent in the Certificate of Patent Term Extension and in the Official Gazette.

In addition, Patentee requests expedited issuance of the Certificate of Patent Term Extension.

Attorney Docket No. A35066 072261.0131
PATENT

Patentee believes that no fee is required in connection with this submission. However, should any fee be required or any overpayment made, the Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account 02-4377. A duplicate copy of this paper is provided.

Respectfully submitted,
BAKER BOTTS L.L.P.

By
Lisa B. Kole
Patent Office Reg. No. 35,225

Attorney for Patentee

30 Rockefeller Plaza
New York, NY 10012-4498
(212)-408-2500

J5066

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

MAR 22 2004

Lisa B. Kole
Baker & Botts LLP
30 Rockefeller Plaza
New York NY 10112

Re: Patent Term Extension
Application for
U.S. Patent No. 4,784,950

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,784,950, which claims the drug product NOVOSEVEN® (rhFVIIa) and methods of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

The period of extension, if calculated using the Food and Drug Administrations determination of the length of the regulatory review period published in the Federal Register of 68 Fed. Reg. 3534, pursuant to 35 U.S.C. § 156(c), would be:

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (2,904 - 171) + 1,050
= 2,417 days (6.6 years)

Since the regulatory review period began May 29, 1988, before the patent issue date (November 15, 1988), the period from May 29, 1988 until and including November 15, 1988 has not been included in the above determination. (See 35 U.S.C. 156(c)("the regulatory review period...which occurs after the date the patent issued.") No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitation of 35 U.S.C. § 156(g)(6)(A), however, operates to reduce the period of extension determined above to a period of five years.

The14 year limitation of 35 U.S.C. § 156(c)(3) does not further limit the term of the extension in the present situation. (The approval date was March 25, 1999, thus the 14 year limit would be March 25, 2013. Since March 25, 2013 is after November 15, 2010, the 14-year limit does not apply.)

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,784,950
Granted:	November 15, 1988
Applicant:	Hagen et al.

U.S. Patent No. 4,784,950

Owner of Record:	~~ZymoGenetics, Inc.~~ Novo Nordisk Health Care AG
Title:	Expression of Factor VII Activity in Mammalian Cells
Classification:	435/068
Product Trade Name:	NOVOSEVEN® (rhFVIIa)
Term Extended:	Five Years
Extended Expiration Date	November 15, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

FDA Docket No.:NOVOSEVEN® (rhFVIIa)
RE: 99E-5112

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MARCH 30, 2004

PTAS *700074119A*

BAKER BOTTS L.L.P.
CARMELLA L. STEPHENS
30 ROCKEFELLER PLAZA - 44 FL.
NEW YORK, NY 10112

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 03/24/2004 REEL/FRAME: 014455/0539
NUMBER OF PAGES: 7

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
ZYMOGENETICS, INC. DOC DATE: 09/28/2000

ASSIGNEE:
NOVO NORDISK HEALTH CARE AG
UNTERE HESLIBACHSTRASSE 46
ZURICH KUSNACHT, SWITZERLAND
CH-
8700

SERIAL NUMBER: 06810002 FILING DATE: 12/16/1985
PATENT NUMBER: 4784950 ISSUE DATE: 11/15/1988

014455/0539 PAGE 2

SAUNDRA BALLENGER, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

FILE NO. A35066 072261.0131

RECORDATION FORM COVER SHEET
PATENTS ONLY

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):
ZymoGenetics, Inc.
Additional name(s) of conveying party(ies) attached?
[ ] Yes [✓] No

2. Name and address of receiving party(ies)
Name: Novo Nordisk Health Care AG

Address: Untere Heslibachstrasse 46

City: Zurich Kusnacht State: Zip: CH-8700
Additional name(s) and address(es) attached? Country: Switzerland
[ ] Yes [✓] No

3. Nature of conveyance:

[✓] Assignment [ ] Merger
[ ] Security Agreement [ ] Change of Name

[✓] Other: First assignment recorded at Reel/frame 004533/0482
Execution Date: September 28, 2000

4. Application number(s) or patent number(s) 4,784,950

If this document is being filed together with a new application, the execution date of the application is

A. Patent Application No.(s)

B. Patent No.(s)

Additional numbers attached? [ ] Yes [✓] No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name:

BAKER BOTTS L.L.P.
30 Rockefeller Plaza - 44 Fl.
New York, NY 10112

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41): $ 40

[ ] Enclosed
[✓] Authorized to be charged to deposit account

8. Deposit account number:
02-4377 (Charge any additional fees to this account)
(Attach duplicate copy of this page if paying by deposit account)

DO NOT USE THIS SPACE

9. Statement and signature

To the best of my knowledge and belief, the foregoing instrumentation is true and correct and any attached copy is a true copy of the original document.

Carmella L. Stephens — Name of Person Signing

Carmella L. Stephens — Signature

March 24, 2004 — Date

Page 1 of 2

Total number of pages including cover sheet, attachments and document:

Assignment of Patents and of June 1, 1984 Agreement Relating to Human Blood Coagulation Factors as Amended

This Assignment Agreement of September 28, 2000, (the "Agreement") governs the transfer of certain rights and obligations of ZymoGenetics, Inc., a Washington corporation having a principal place of business at 1201 Eastlake Avenue East, Seattle, Washington 98102 ("ZGI") to Novo Nordisk Health Care AG, a Swiss corporation having a principal place of business at Untere Heslibachstrasse 46, CH-8700 Küsnacht, Zurich, Switzerland("NN").

WHEREAS, ZGI is engaged generally in the research and development of biopharmaceutical products;

WHEREAS, ZGI and Novo Industri A/S entered into an agreement dated June 1, 1984 relating to human blood coagulation factors, and amended the same on November 7, 1984 (hereinafter, the "Factor VII Agreement"); and

WHEREAS, ZGI wishes to assign to NN the Factor VII Agreement and transfer to NN all of ZGI's right, title and interest in the Licensed Patents (as defined below);

NOW THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

ARTICLE 1
Definitions

SECTION 1.1. "Effective Assignment Date" means: September 28, 2000.

SECTION 1.2. "Licensed Patent" means: any patent or patent application that is within a patent family listed in Appendix 1, except 83-23C2 (US Patent Application No. 07/765,452 only as it applies to Factor IX and not to Factor VII). Said patent and patent applications shall include but not be limited to selection patents, provisional applications, patent applications, divisionals, continuations, continuations-in-part, reissues, re-examinations and extensions and foreign counterparts of the foregoing. Extensions of patents shall include; (a) extensions under the U.S. Patent Term Restoration Act, (b) extensions of patents under Japanese Patent Law, (c) Supplementary Protection Certificates for members of the European patent convention and other countries in the European Economic Area, and (d) similar extensions under any applicable law anywhere in the World.

SECTION 1.3. "Product" means: NovoSeven® or any other product encompassed by the Licensed Patents.

ARTICLE 2
Assignment of Factor VII Agreement

SECTION 2.1. Assignment. As of the Effective Assignment Date, ZGI hereby irrevocably and unconditionally conveys, transfers, assigns and delivers to NN all of ZGI's right, title and interest in and to the Factor VII Agreement and the Licensed Patents.

SECTION 2.2. Assumption. NN hereby irrevocably and unconditionally accepts the assignment set forth in SECTION 2.1 hereof, assumes all of ZGI's obligations under the Factor VII Agreement, agrees to perform all of ZGI's duties under the Factor VII Agreement, agrees to be bound by the terms of the Factor VII Agreement, and releases ZGI from further obligation and liability under the Factor VII Agreement.

ARTICLE 3
Assignment Fee

SECTION 3.1. Assignment Fee. On, before or within thirty (30) business days after the Effective Assignment Date, NN shall pay to ZGI an assignment fee of eighty one million United States dollars (US$81,000,000), less the amount of any royalty payments actually received by ZGI from NN or an affiliate of NN during the year 2000 and before the Effective Assignment Date that are attributable to year 2000 Licensed Product sales. NN or an affiliate of NN shall prepare this calculation no later than fifteen (15) days after the Effective Assignment Date. If requested by ZGI, the calculation shall be verified by PricewaterhouseCoopers, Denmark.

SECTION 3.2. Agreement Null and Void. This Agreement shall be null and void if the assignment fee set forth in SECTION 3.1 is not timely paid.

ARTICLE 4
Transfer of Licensed Patents

Upon receipt of the assignment fee set forth in ARTICLE 3 and following the Effective Assignment Date, ZGI shall begin the process of the registration of the transfer of ownership and/or control of the Licensed Patents to NN, which process may include execution of assignment documents, copying of files, updates on the status of ongoing interference proceedings and/or other related activities. Within thirty (30) days following the Effective Assignment Date, a patent representative of NN and ZGI, respectively, shall discuss and agree upon the action items, responsible party and expected completion date for all patent transfer activities. The parties will use their best efforts to ensure that the transfer process, executed in accordance with the mutually agreed upon plan, will be completed as soon as practically possible after the date on which the patent representatives met. NN shall reimburse ZGI for its

documented out of pocket expenses, incurred in effectuating the transfer of Licensed Patents to NN within thirty (30) days of NN's receipt of ZGI's invoice detailing such expenses.

ARTICLE 5
Warranty by ZGI

ZGI warrants that it, to the best of its knowledge and belief in the absence of specific current inquiry, owns the entire right, title and interest in the Licensed Patents, that the inventors listed in the Licensed Patents are accurately and completely listed in all material respect and that it has given to NN, its parent company Novo Nordisk A/S or other affiliates owned by Novo Nordisk A/S all information relating to Licensed Patents in ZGI's possession or under its control which ZGI deems material to this Agreement.

ARTICLE 6
Indemnification

SECTION 6.1. Personal Injury or Property Damage. NN shall indemnify and hold ZGI harmless from and against any and all claims, judgments, costs, awards, expenses (including, but not limited to, any attorney's fees) or liability of any kind arising out of personal injury or property damage caused or alleged to be caused by NN's or NN's affiliates' exercise of rights to Licensed Patents. In addition, NN or NN's affiliates shall assume all obligations for warranties and product liability claims that accompany or result from the sale or use of any Product, and shall indemnify and hold ZGI harmless from and against any and all claims, judgments, costs, awards, expenses (including, but not limited to, any attorney's fees) or liability of any kind arising from customers and relating to such warranty obligations or product liability claims. NN's obligation to indemnify ZGI under this SECTION 6.1 shall not apply in case of negligence or willful misconduct by ZGI.

SECTION 6.2. Insurance. NN shall maintain and cause its affiliates to maintain appropriate product liability insurance with respect to development, manufacture and sale of Products in such amount as NN or its affiliates customarily maintains with respect to sales of its other products. NN and its affiliates shall maintain such insurance for so long as NN or its affiliate continues to manufacture or sell Products, and thereafter for so long as NN or its affiliates customarily maintains insurance with respect to sales of its other products.

SECTION 6.3. Indemnification by ZGI. ZGI shall indemnify and hold NN and Novo Nordisk, harmless from and against any and all claims, judgments, costs, awards, expenses (including, but not limited to, any attorney's fees) or liability of any kind arising from breach of a warranty of ZGI.

SECTION 6.4. Survival. The obligations of this ARTICLE 6 shall survive the expiry or termination, for whatever reason, of this Agreement.

ARTICLE 7
General

SECTION 7.1. Governing Law. This Agreement shall be governed in all respects by the laws of the State of New York.

SECTION 7.2. Dispute Resolution. ZGI and NN will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this Agreement, which cannot be solved amicably by the Parties, shall be referred to arbitration as described below. However, before a dispute or difference is referred to arbitration, the CEO of ZGI and the CEO of Novo Nordisk A/S (through a request to this extent from NN) shall make a final attempt to solve the matter amicably. All disputes arising out of or in connection with the present contract shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with the said Rules. The arbitration shall take place in New York City and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both ZGI and NN. ZGI and NN bind themselves to carry out the awards of the arbitrator.

SECTION 7.3. Entire Agreement. This Agreement and the Appendices hereto constitute the entire agreement between the parties and supersede all prior oral and written agreements, understandings or arrangements relating to the subject matter hereof. No addition to or modification of any provision of this Agreement shall be binding upon the parties, unless made in writing and signed by a duly authorized representative of each of the parties.

SECTION 7.4. Severability. The parties agree that, if any provision of this Agreement shall for any reason be held to be invalid or unenforceable, such provision shall be enforced to the maximum extent permitted by law and the parties' fundamental intentions hereunder, and the remaining provisions hereof shall not be affected, impaired or invalidated and shall continue in full force and effect.

SECTION 7.5. Headings. The article and section headings contained herein are for reference only and shall not be considered a part of this Agreement, nor shall they in any way affect the interpretation hereof.

SECTION 7.6. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, NN and ZGI have caused this Agreement to be executed in their names by their properly and duly authorized officers or representatives.

signed after Extraordinary Shareholders Meeting and Board Meetings were held:

NOVO NORDISK HEALTH CARE AG

Urs N. Pfluger
General Manager

Klaus Ehrlich
Board Member

ZYMOGENETICS, INC.

Bruce L.A. Carter
President & CEO

APPENDIX 1
Licensed Patents

ZGI Patent Family	Novo Nordisk A/S References	Parent Application	Includes US Patent	Derwent Title
83-23, except 83-23C2 (US Patent Appl. No. 07/765,452 only as it applies to Factor IX and not to Factor VII)	3138	US application Ser. No. 724,311	4,784,950	DNA construct used to transfect hosts to produce protein which activates to give factor VIIa
89-20	None	US application Ser. No. 471,313	5,288,629 5,824,639	New modified factor VII to treat and prevent coagulation disorders – has a reduced susceptibility to activation by plasma factor Xa and inhibits clotting activity of wild type factor VIIa
90-07	3598 4607 5214 5295	USSN 07/662,920	5,788,965 5,817,788 5,833,982 6,039,944 5,861,374	Modified factor VII for use as an anti-coagulant – inhibits tissue factor activity but is unable to activate plasma factors X or XI
None	3129	DK87/03235 (completed as WO 88/10295	5,580,560	Mutated human factor VII or VIIa proteins - with amino acid substitutions

FISH & RICHARDSON P.C.

1425 K STREET, N.W.
11TH FLOOR
WASHINGTON, DC 20005

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202 783-2331

Web Site
www.fr.com

Date April 19, 2004

To Ms. Karin L. Ferriter
U.S. Patent and Trademark Office
Office of Patent Legal Administration

Telephone:

Facsimile number 703-872-9411

Phone number 703-306-3159

From Scott B. Markow

Re Patent Term Extension
Our Ref.: 00231-112001

Number of pages including this page 28

Message